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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,753	07/03/2003	Brenda Reeve	GOUD:032US	5649

7590 07/26/2007

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,753	REEVE, BRENDA	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2007 has been entered.

Applicant's arguments over the 35 U.S.C. 112 first rejection of claims 18-24 is persuasive due to the cancellation of the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-7, 10-19, 21-22, and 23 over Gervais (Pat. No. 6,340,695 - IDS) in view of Apfel (PONV Research – reference provided) is persuasive. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 8, 9, and 20 over Gervais (Pat. No. 6,340,695 - IDS) in view of Apfel (PONV Research – reference provided) and Ansel et al. is persuasive. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the Obvious Double Patenting rejection over U.S. Patent No. 6,340,695 is not fully persuasive. Therefore, the rejection is herewith modified to incorporate added limitations.

Claims 1-12 and 14-17 are pending.

Upon further consideration of the amended claims, the following rejections are made:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to further limit independent claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-12, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gervais (Pat. No. 6,340,695 - IDS) in view of Apfel et al. (A Simplified Risk Score for Predicting Postoperative Nausea and Vomiting. Anesthiology. 1999;91,693-700 – reference provided).

Gervais teaches a rapid onset formulation comprising pyridoxine HCl and doxylamine succinate useful in the treatment of nausea and vomiting comprising admistration of a therapeutically effective amount of the composition (see, column 1 lines 5-11, column 11 lines 1-3, and specifically claim 27).

The reference does not specifically teach "reducing post-surgical vomiting" or "treating post-surgical vomiting" comprising the administration before, during after (at regular intervals), before anesthesia, on an outpatient bases, on an evening prior to, a morning of the day of, immediately after surgery, as recited in claims 1-6, 13, 15-16. However, the reference teaches the formulation of Doxylamine succinate and pyridoxine hydrochloride are used in the human and veterinary fields of medicine whenever symptoms of nausea and/or vomiting require medical intervention (column 2, lines 56-59)." The reference teaches oral dosage forms (column 2, lines 61-63), as recited in claim 7. Additionally, the reference teaches in Example 1 a formulation wherein pyridoxine HCl and doxylamine succinate each weigh 10 mg/ tab, as recited in claim 11. The formulation and its components are in pharmaceutically acceptable carriers (e.g., magnesium trisilicate) (column 4, see Table 1), meeting the limitation of claim 10. The treatment of nausea and vomiting is especially, but not limited to, during pregnancy (column 1 lines 5-11), meeting the limitation of claim 14. The limitation "at substantially the same time," recited in claim 17, are met because the reference teaches the formulation in a tablet, pill or encapsulated beads or solution. Hence, the components are administered at "substantially the same time" in any form recited above.

Anpfel et al. is used to show that PONV (postoperative nausea and vomiting) has been known in the prior art to be associated with general anesthesia. Anpfel further teaches a prophylactic antiemetic strategy should be considered when a patient is known to be at risk of PONV.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Doxylamine succinate and pyridoxine HCl formulation to reduce post-surgical vomiting in patients undergoing general anesthesia because the reference teaches the treatment of vomiting and nausea in general and Anpfel et al. teaches a prophylactic antiemetic strategy should be considered when a patient is known to be at risk of PONV. The motivation to administer the said formulation is because the prior art teaches the ingredients in treating nausea and vomiting (see claim 25, column 10, lines 62-64, and column 2, lines 56-61) and Anpfel et al. teaches general anesthetics associated PONV "increases patients' discomfort and also increase costs and unwarranted side effects." Therefore, a skilled artisan would have reasonable expectation of treating post operative nausea and vomiting because Gervais teaches that the said formulation can be administered whenever symptoms of vomiting and nausea require medical intervention and Anpfel teaches PONV (postoperative nausea and vomiting) has been known in the prior art to be associated with general anesthesia.

In reference to Claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Gervais compound by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Gervais' final formulation is because he would have had a reasonable

expectation of success in achieving the safest clinical outcome.

Claims 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gervais (Pat. No. 6,340,695 - previously presented) in view of Apfel et al. (A Simplified Risk Score for Predicting Postoperative Nausea and Vomiting. Anesthiology. 1999;91,693-700 – reference provided) as applied to claims 1-7, 10-12,14-17 above, and further in view of. Ansel et al. (previously presented).

Gervais and Apfel are discussed above.

The preferred formulation of the Gervais invention is in the form of an oral dosage form such as a tablet, pill or encapsulated beads or solution (column 2, lines 61-64). Further, the art teaches in the "most preferred embodiment, the formulation contains a core coated with an aqueous enteric coating. The core comprises the active ingredients pyridoxine HCl and doxylamine succinate (column 3, lines 39-42).

Gervais does not specifically teach a delayed release formulation.

Ansel et al. teaches delayed release products usually are enteric-coated tablets or capsules designed to pass through the stomach unaltered, later to release their medication within the intestinal tract (page 229, column 1, first paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the identical enteric-coated tablet with the composition. The motivation to make such an incorporation is because Gervais teaches the preferred embodiment of the invention is a formulation that is entirically coated and further by Ansel's teaching that delayed release products are usually enterically-coated.

The skilled artisan would have reasonable expectation of producing a similar composition with similar efficacy and delayed release properties.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, and 14-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-29, and 30 of U.S. Patent No. 6340695) in view of Apfel et al. (A Simplified Risk Score for Predicting Postoperative Nausea and Vomiting. Anesthiology. 1999;91,693-700 – reference provided).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application recites a method of treating nausea and vomiting comprising administering a therapeutically effective

amount of an enterically-coated pyridoxine HCl and doxylamine succinate rapid onset formulation, whereas the instant claims are to method of reducing post-surgical vomiting comprising administering to a patient undergoing general anesthesia a therapeutically effective amount of pyridoxine HCl and doxylamine succinate. To one of ordinary skill in the art it would be obvious to administer the identical composition with the expectation of producing similar efficacy and results, especially since the Anpfel reference teaches PONV (postoperative nausea and vomiting) has been known in the prior art to be associated with general anesthesia.

Response to Arguments

Applicant's arguments with respect to the Apfel reference have been considered and is persuasive but are moot in view of the new ground(s) of rejection.

Applicant argues that the Gervais formulation requires medical intervention i.e., on existing symptoms. Further Applicant argues, "Gervais does not teach or suggest that the formulation of doxylamine succinate and pyridoxine hydrochloride is or should be used "before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting" as recited in instant claim 1." The arguments are drawn to limitations previously not presented. However, Examiner points to the new rejections above, in which the newly added limitation are addressed.

Applicant's arguments with respect to the Apfel rejections have been considered but are moot in view of the new ground(s) of rejection.

Additionally, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the preferred formulation of the Gervais invention is in the form of an oral dosage form such as a tablet, pill or encapsulated beads or solution (column 2, lines 61-64). Further, the art teaches in the "most preferred embodiment, the formulation contains a core coated with an aqueous enteric coating. The core comprises the active ingredients pyridoxine HCl and doxylamine succinate (column 3, lines 39-42).

Gervais does not specifically teach a delayed release formulation.

Ansel et al. teaches delayed release products usually are enteric-coated tablets or capsules designed to pass through the stomach unaltered, later to release their medication within the intestinal tract (page 229, column 1, first paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the identical enteric-coated tablet with the composition. The motivation to make such an incorporation is because Gervais teaches the preferred embodiment of the invention is a formulation that is enterically coated and further by Ansel's teaching that delayed release products are usually enterically-coated.

The skilled artisan would have reasonable expectation of producing a similar composition with similar efficacy and delayed release properties.

Examiner acknowledges the arguments drawn to "surprising and unexpected results and satisfying a long-felt need." However, the arguments are not found persuasive in view of the rejections recited above.

Applicant's arguments with respect to the ODP have been considered but are moot in view of the modified rejections.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER